REMARKS

Claims 1-14, and 19 are pending in the instant application. Claims 1-14 and 19 have been rejected by the Examiner. By the above amendments, independent Claims 1, 6 and 11 have been amended to more particularly point out and distinctly claim the subject matter which applicants regard as the invention. More particularly, Claims 1, 6 and 11 have been amended to limit the indication to dementia. Applicants submit that the amendments limiting the claims to the treatment of dementia are being made solely to advance the prosecution of the instant application and are not in any way to be construed as an admission that the canceled material is unpatentable. Thus, Applicants reserve the right to pursue coverage of the canceled material by filing a continuation or a divisional application at an appropriate time in the future. After entry of the amendments, Claim 1-14 and 19 will remain pending and under consideration.

The Examiner has rejected Claims 1-14 and 19 under 35 U.S.C. §103(a) as being unpatentable over Fulton et al. in view of Yankner et al. (US Patent No. 6,080,778). The Examiner states:

> Fulton et al. disclose that Galanthamine is effective for treatment of Alzheimer's disease (See entire document).
>
> Yankner et al. disclose the administration of statins for treatment of Alzheimer's disease (Column 3, lines 20-53). . . .
>
> The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of Galanthamine and statins for treatment of Alzheimer's disease. However, the prior art amply suggests the same as the prior art disclose that both are effective for treatment of Alzheimer's disease. As such, one of ordinary skill in the art would have been motivated to combine the prior art with the expectation that the combination would be effective for treatment of Alzheimer's disease. Further, one of ordinary skill would have been motivated to use various amounts, including the amounts claimed, depending on the effectiveness of the treatment of Alzheimer's disease.
>
> Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Applicants respectfully traverse this rejection.

In order to move the present application to allowance but without conceding the correctness of the Examiner's rejection, Applicants submit herewith a Declaration under 37 C.F.R. §1.132 of Joan Amatniek, M.D. ("Amatniek Decl.").

As Dr. Amatniek's declaration shows, on the basis of post hoc analyses of several double blind clinical trials of galantamine hydrobromide, Applicants surprisingly found that there was a synergistic positive effect on cognitive function in patients receiving galantamine + statin, as compared to those receiving either galantamine alone or placebo + statin. Amatniek Decl. ¶¶ 8, 10, 12, 14. Additionally, the data from the initial pivotal trials (GAL-INT1, GAL-USA-1 and GAL-USA-10) unexpectedly and surprisingly showed that patients receiving galantamine + statin were above their baseline scores for 4 more months compared to patients receiving galantamine alone, which is also consistent with a synergistic effect; patients receiving galantamine + statin returned to their original cognitive status at approximately 14 months, as compared to 10 months for the patients on galantamine alone and 3 months for patients on placebo + statin. Amatniek Decl. ¶¶ 8, 10, 14. Furthermore, at 18 and 24 months, a sustained efficacy difference in favor of galantamine + statin compared to galantamine alone appears to exist, which is also consistent with a synergistic effect. Amatniek Decl. ¶¶ 8, 10, 14. These unexpected findings rebut any *prima facie* case of obviousness, as one of ordinary skill in the art at the time the invention was made would not have expected the combination of galantamine + statin to have a synergistic effect on cognitive function of AD patients, or to delay by an additional 4 months the time to cross baseline as compared to patients receiving galantamine alone. Moreover, when the data from the post hoc analyses were presented to nine experts in the field of statins, galantamine, and Alzheimer's disease during the first two weeks of June 2007 under terms of confidentiality, the experts were surprised by the findings. Amatniek Decl. ¶¶ 14. Since the claimed invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made, Applicants respectfully request that the Examiner withdraw the rejection of Claims 1-14 and 19 under 35 U.S.C. §103(a).

Finally, Applicants' attorney wishes to inform the Examiner that it has recently been determined that Dr. Amatniek is a co-inventor of the claimed subject matter of the instant application. An amendment to correct inventorship to add Dr. Amatniek as a co-inventor is being prepared and will be submitted shortly for the Examiner's consideration. The error in failing to name Dr. Amatniek as a co- inventor arose through error without deceptive intent on the part of Dr. Amatniek.

In view of the above amendments and remarks, Applicants maintain that the application is in condition for allowance and passage to issue is earnestly requested.

Applicants do not believe any fees are associated with the filing of this Response. However, in the event applicants are mistaken, authorization is hereby provided to charge any and all fees required by this paper to Deposit Account No. 10-0750/JAB1705USPCT/MAA.

Respectfully submitted,

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